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March 5, 2008.

David Saliwanchik

David R. Saliwanchik, Patent Attorney

COMMUNICATION
Patent Application
Docket No. GJE-68
Serial No. 09/856,944

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner	:	Vera Afremova
Art Unit	:	1651
Applicant	:	John Ernest Hart
Serial No.	:	09/856,944
Filed	:	May 30, 2001
Conf. No.	:	6466
For	:	Isolated Material Having An Anti-Organotrophic Effect

Mail Stop APPEAL BRIEF-PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

COMMUNICATION

Sir:

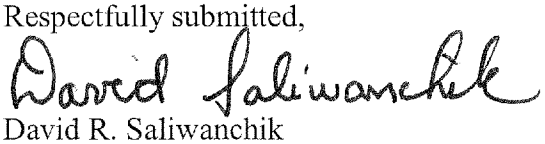
With regard to the Examiner's Answer dated November 29, 2007, the applicant refers the Commissioner to the Response filed by the applicant on September 12, 2005, a copy of which accompanies this communication. This Response was filed in response to the Examiner's Answer dated July 12, 2005. The substantive portions of the Examiner's two Answers are identical and, thus, the applicants have nothing further to add to their Response that was filed September 12, 2005. The applicant respectfully asserts that the file for this Appeal is complete at this time.

Accordingly, the applicant respectfully requests consideration of the merits of this Appeal.

The Commissioner is hereby authorized to charge any fees under 37 CFR 1.16 or 1.17 as required by this paper to Deposit Account 19-0065.

The applicants invite the Examiner to call the undersigned if clarification is needed on any aspect of this communication.

Respectfully submitted,



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DRS/yvs

Attachment: Response filed September 12, 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner	:	Vera Afremova
Art Unit	:	1651
Appellant	:	John Ernest Hart
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Mail Stop Appeal Brief-Patents
Honorable Commissioner of Patents
Attention: Board of Patent Appeals and Interferences
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO EXAMINER'S ANSWER

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:
Mail Stop Appeal Brief-Patents,
Honorable Commissioner of Patents, P.O. Box 1450
Alexandria, VA 22313-1450 on September 12, 2005.

David Saliwanchik

David R. Saliwanchik, Patent Attorney

Response to Examiner's Answer

With regard to Sections (1) through (9) of the Examiner's Answer (hereinafter, "the Answer" or "the Office") no areas of disagreement between the Appellant and the Patent Office are evident.

With regard to Section (10) of the Answer, the grounds for rejection are essentially a re-iteration of the rejections set forth in the Final Rejection. The Appellant has, in his Appeal Brief, fully addressed each of these grounds of rejection.

With regard to Section (11) of the Answer, in which the Answer ostensibly responds to the Appellant's arguments, the Appellant notes what appear to be new issues based on misunderstandings by the Office of the arguments and/or claim language being presented by the Appellant. Despite misconstruing the claim language and misunderstanding the Appellant's arguments, the Office still has utterly failed to rise to the challenge of identifying in the prior art any disclosure of organ mass reduction, a critical characteristic of the Appellant's calimed material. The Answer clings to a misinterpretation of the diZerega reference despite the fact that diZerga himself clearly states that his composition only causes a lessened increase (of the ovaries alone). As there is no organ shrinkage whatsoever in diZerega, this patent does not anticipate or render obvious the Appellant's organ-reducing material.

Below, the Appellant addresses, in the order raised by the Office, the issues raised in the Office's "Response to Argument."

A.1. The claimed material must be inducible post-oestrus by chlomiphene.

The Answer states at page 7:

> [a]ppellant's argument that the material must be inducible post-oestrus by chlomiphene is not convincing because the as-filed specification clearly describes that "this step is optional" and that "depending on factors such as the age of sheep, clomiphene induction may be unnecessary." (emphasis in original)

Unfortunately, the Office has misunderstood the Appellant's argument. The Appellant is not stating that the claimed material must be "induced" by clomiphene in order to be produced. When the Appellant states that his material "must be inducible post-oestrus by clomiphene" what is clearly meant is that, in order to fall within the scope of the Appellant's claim, the material must be inducible post-oestrus by clomiphene. Conversely, a material that is not inducible post-oestrus by clomiphene would not be covered by the Appellant's claims. Accordingly, a material that may have existed in the prior art but which is not inducible by clomiphene is clearly not the same as (and does not anticipate) the claimed material. Thus, this characteristic constitutes a clear distinction from the prior art material, FRP not being inducible by clomiphene, as shown by diZerega's own data (figure 18 and column 24 lines 8-19). The Appellant is not stating that induction by clomiphene is necessary in order to produce the material. Rather, the fact that clomiphene does induce the claimed material is a point of distinction compared to the prior art. Thus, the remarks at the bottom of page 7 and top of page 8 of the Answer are non-responsive to the Appellant's argument.

Further, the first full paragraph on page 8 of the Answer does not support the outstanding rejection or address the Appellant's arguments. The Appellant respectfully requests clarification of how this discussion regarding clomiphene supports the rejection. In passing, the Appellant wishes to note that the statement by the Office at page 8 of the Answer that "[c]lomiphene is a known generic drug for induction of ovulation" is a gross over-simplification as well as misleading in the context of the current case. Clomiphene is indeed known for inducing ovulation in humans; hwoever, to induce ovulation it is provided pre-ovulation, *e.g.* on days 5-9 (see diZerega column 23 lines 7-8). In contrast the present invention relates to a surprising and unexpected consequence of treatment with clomiphene post-oestrus – this cannot prouce ovulation, but it does induce production of the claimed composition.

The Answer then goes on to state at page 8:

> Appellant further argues that the claimed material has been found to be induced by clomiphene independent of ovulation because clomiphene cannot re-induce ovulation after ovulation has occurred in mammals having oestrus cycle or in mammals having reoccurring ovulation (appeal brief page 4). However, the

> limitation as argued is not within the scope of the instant claims and this is not supported by disclosure in the instant as-filed specification. The claims are drawn to the use of "post-oestrus" mammals and thus, the claim specific mammals have to have oestrus cycle and to ovulate. Therefore, this feature ("induced by clomiphene independent of ovulation") as argued is not within the scope of the instant claims as written. (emphasis in original)

Again, the Office appears to misunderstand both the meaning of the claim as well as the import of the Appellant's argument. The position that the Appellant has consistently taken is that the production of micrin is not caused by ovulation. Thus, micrin production occurs "independent" of ovulation. Certainly this does not preclude a temporal relationship between the two events. For example, Labor Day occurs after Memorial Day, but the two holidays are independent events. The Appellant's composition can be induced by clomiphene, even post-oestrus, thus the production of this composition is not caused by ovulation — it is independent of ovulation. The Appellant's claims specify that the claimed composition can be induced by clomiphene "post-oestrus." In the post-oestrus phase ovulation cannot occur again; therefore, the production of the claimed compound is independent of ovulation.

The Answer goes on to state at page 9:

> [e]ven if the feature of the appellant's invention as argued such as material that is directly induced by clomiphene and that is independent of ovulation might distinguish over the prior art of record, this feature/characteristic of the claimed material is not described in the as-filed specification. The appellant's presently claimed material is poorly characterized in the instant as-filed specification and it is not materially and functionally different from the prior art material. An advantage not disclosed in the application cannot be urged as basis for allowing claims. *In re Lundberg* 117 USPQ 190 (CCPA 1958).

Once again it is difficult to understand the point the Office is trying to make. The limitations to which the Office refers are in the claims and do distinguish over the prior art. Furthermore, there is clearly support in the specification for these limitations. Support for these limitations can be found at, for example, page 1 lines 31-33 (for induction by clomiphene) and page 3, line 33 and page 5, line 32 to page 6 line 2 (for "post-oestrus").

With regard to the Office's reliance on *In re Lundberg*, the Appellant respectfully submits that the current case is easily distinguished from the situation in *Lundberg*. First, the attributes of the Appellant's composition that are advantageous are clearly set forth in the as-filed specification. This includes, most notably, the ability to reduce organ mass including non-gonadal organs in a live adult mammal. Furthermore, the *Lundberg* case involved an obviouness rejection, which the applicant was trying to overcome by demonstrating unexpected advantages. Please note that the current Appellant is not necessarily asserting that, for example, the induction by clomiphene, is an "advantage" of the claimed compound. Rather, this characteristic, and others noted by the Appellant, are distinctions from the prior art that clearly establish that the prior art does not disclose the current composition. Therefore, the outstanding anticipation rejection is unfounded. Furthermore, nothing in the cited reference suggests the claimed material. Simply put, one skilled in the art could not arrive at the Appellant's composition from the teachings of diZerega. Thus, the outstanding obviousness rejection is also improper.

A.2. The claimed material reduces the mass of organs, including non-gonadal organs in a live adult mammal.

With regard to the claim limitation requiring that the claimed material cause a reduction in the mass of body organs, the Office continues to confuse a "reduction" in organ mass with "a decrease in an increase in organ mass." One skilled in the art would not be similarly confused.

diZerega reported that some test solutions inhibited stimulated ovarian regrowth. Indeed, diZerega himself summarized the findings as: "In Examples One through Three protein(s) in ovarian venous effluent... inhibited rat ovarian weight gain in response to gonadotropin stimulation." [column 20 lines 29-33]. (emphasis added) Thus diZerega's FRP does not have the capability of reducing organ mass; it merely has the capability of inhibiting the increase of ovarian mass caused by the gonadotropins in the artificial situation of hypophysectomised rats.

This issue has been thoroughly addressed by the Appellant in his previous Responses and his Appeal Brief, so there is no need to repeat here the detailed analysis of diZerega. Suffice it to say

that any person skilled in the art (in fact, any person at all who has read the entire diZerega article) could only conclude that the diZerega compound does not reduce organ mass.

The composition claimed by the Appellant produces a decrease of mass in body organs, including non-gonodal organs. This is a very surprising property and quite different to that of the cited reference. The ability to reduce organ mass is explicitly required by the Appellant's claims; this characteristic is absent from the diZerega teachings.

The Office then states at page 10 of the Answer:

> Appellant also argues the ability of the claimed material to reduce the mass of body organs including non-gonadal organs. The prior art clearly demonstrates effects of blood fractions on the gonadal organs such as ovaries. Yet, by the virtue of the open language "including" the claimed invention is open to limitations drawn to both non-gonadal and gonadal body organs including ovaries. Thus, the argument is not found persuasive with respect to the instant claims. (emphasis in original)

The Appellant respectfully submits that this statement reflects a misunderstanding of the claim language. The claim requires that the material be able to reduce the size of organs that are non-gonadal. There is no "openness" or ambiguity.

Finally with regard to the issue of organ mass, the Office again stretches (or exceeds) the limits of credibility by taking the position that 3 week old rats are adults because "they had body organs developed enough to evaluate their weights." Surely the Office cannot be asserting that the ability to weigh body organs is a test for adulthood. In this regard, please note that the American Heritage Dictionary 3rd Edition defines "adult" as "fully developed, mature." Webster's Third New International Dictionary defines "adult" as "fully developed (as in size, strength, or intellectual capacity): fully mature: grown-up." No person skilled in the art would consider 3 week old rats to be "adults."

A.3. The material is purified from ovarian venous blood post-oestrus.

With regard to the timing of the collection of the material, the Examiner's Answer states:

> [t]he blood collection was done in the middle of cycles and, thus, it is reasonable believe that blood collection was done at or after ovulation time in the ovulatory mammals and, thus, "in a mammal post-oestrus" within the meaning of the claims.

diZerega obtained FRP from blood taken "on days 12-14 after the onset of the last menstrual period", which would be readily understood by a person skilled in the art to correspond to the pre-ovulatory phase (see column 8 lines 66-67 and column 9 lines 13-15). That this point in time is pre-ovulation is clear from the descriptions of figure 2 and figure 6 [column 3 lines 49-50 and column 4 lines 15-16], and this was confirmed by the measured levels of 17β-estradiol [column 9 lines 14-15].

Di Zerega found there was an inhibitory effect from a material found in such pre-ovulation venous blood, but also found that there was no such effect from ovarian venous blood from anovulatory patients, and indeed from ovarian venous blood from the contralateral ovary [column 10 lines 53-60]. There is therefore certainly no expectation that diZerega's FRP material might be obtained post-ovulation, that is, after the pre-ovulatory surge in gonadotropin which it is supposed to modulate.

In contrast, the composition of the subject invention is obtained post-oestrus. This limitation of the Appellant's claim is not met by the diZerega reference nor does diZerega provide any suggestion that such a material may exist, or if it did exist, what characteristics (such as the ability to reduce organ mass) it would have.

B. The Claimed Compoisition is not taught or suggested by diZerega.

To address the Appellant's argument the Office states:

> [a]rguments based on some unidentified and/or undisclosed characteristics do not provide sufficient grounds for the evidence to the contrary to the claim rejection under 35 U.S.C. 103(a) as obvious over US 4,734,398.

Although the precise meaning of this statement is largely obfuscated by the awkward sentence structure, the Appellant re-iterates that his material, as claimed, is readily distinguishable, based on clearly identified and disclosed characteristics, from the material described in the cited reference.

The Answer again incorrectly states that FRP and the claimed material have "identical molecular weights" further stating that: "The prior art ovarian venous blood fractions with the same molecular weights were shown to reduce the organ mass weight". These are extraordinary assertions, as the present invention and the citation merely provide ranges for the molecular weights. diZerega suggest that his material may have a molecular weight in the range 14-18 kD [see description of figure 6 in column 4], or possibly 12-15 kD and 22-25 kD [see description of figure 7 in column 4]. Apparently, the diZerega material of interest has a molecular weight somewhere between 12 and 25 kD. So the most that can be said is that the molecular weights are of similar magnitude.

Even more importantly, the prior art material has never been shown to reduce the mass of any organ. The claimed material is further clearly distinguished by being obtained at a different phase in the menstrual cycle and is further distinguished in that it can be induced by clomiphene post-oestrus.

What is abundantly clear from the record is that diZerega does not disclose, either inherently or explicity, a material having the characteristics of the composition claimed by the Appellant. Furthermore, there is absolutely no teaching in diZerega as to how one skilled in the art could arrive at the composition claimed by the Appellant. Without such a teaching, no *prima facia* case of obviousness has been established.

In view of the foregoing, the Appellant urges the Board to reverse the 35 USC §102/103 rejections and that this application be passed to issuance.

Respectfully submitted,

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Attachment: Request for Oral Hearing